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K002471

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: pfm Produkte für die Medizin AG
Address: Wankelstr. 60
50996 Cologne
Germany
CONTACT PERSON: Salvadore F. Palomares, RAC

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:
Trade Name: Jetcan Huber Needle Set
Common Name: Intravascular Administration Set
Classification Name: Same

Equivalent Devices:
Manufacturer: Micro-Med, Inc.
Name: Core-Resistant Huber Infusion Set with and without Y-Site
510(k) #: K950597

Device Description:
The Jetcan Huber Needle Set is a single use, sterile and non-pyrogenic device intended for use as an accessory to deliver solutions and drugs into a patient's vascular implant port. Components used in the sets may be either manufactured by pfm, CPP or purchased from approved contract manufacturers. Components will be assembled into standard configurations or configurations specified by the customer and packaged.

Types of components that may be contained in a set include:

- Tubing
- Clamps
- Y-Site Injection Ports
- Stopcock

Intended Use:
The Jetcan Huber Needle Set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an IV set stopcock, fluid delivery tubing, connectors between parts of the set, an injection site, and a hollow spike to penetrate and connect the tubing to an IV bag or other infusion fluid container.

Biocompatibility:
The materials used to manufacture the Jetcan Huber Needle Set are used in legally marketed devices under comparable conditions of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2000

pfm Produkte fÜr die Medizin AG
C/O Salvadore F. Palomares, RAC
Regulatory Consultant for pfm
154 Via Lampara
Rancho Santa Margarita, California 92688

Re: K002471
Trade Name: Jetcan Huber Needle Sets
Regulatory Class: II
Product Code: FPA
Dated: August 9, 2000
Received: August 11, 2000

Dear Mr. Palomares:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k): K002471

Device Name: **Jetcan Huber Needle Set**

Indications for Use: The Jetcan Huber Needle Set is a device used to administer fluids from a container to a patient's vascular system through an implanted port.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or _____ Over the Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control, and
General Hospital Devices

510(K) NUMBER K002471